Adverse Event Reporting

Introducing New Policies & Procedures on AERs

Department of Health

Developmental Disabilities Division

Provider Training

Posted to Website 1/30/2018

Learning Objectives for Providers

1. Understand the purpose of Adverse Event Reports (AERs)
2. Understand new policies, changes to procedures, and changes to the AER form
3. Understand expectations for Adverse Event reporting

What is an Adverse Event?

- Adverse Event Definition:
  - A critical event or incident that can jeopardize the health and safety of a participant
  - A critical event or incident that can bring harm or create the potential for harm to the participant

Purpose of AERs

Purpose of Adverse Event Reporting

- DDD's system for assuring participant health & welfare (required by Waiver)
- Required by:
  - Chapter 346, HRS, Adult Protective Services
  - Chapter 350-1, HRS, Child Protective Services
  - DDD Policy 3.07, Adverse Event Reporting (approved on 7/5/17)

DDD Adverse Event Report Policy (#3.07)

- Policy provides guidance and clarifies DDD processes for adverse event reporting
- Aligns with other DDD policies*
  - DDD Policy #2.01 – Positive Behavior Supports
  - DDD Policy #2.02 – Restrictive Interventions
  - DDD Policy #2.03 – Behavior Supports Review
  - DDD Policy #2.05 – Mandatory Reporting of Abuse and Neglect

* *All policies are included in Medicaid I/DD Waiver Standards Section 4, Appendices & Resources*

Why are Adverse Event Reports Important?

- Ensure that immediate and appropriate action was taken to safeguard the participant
- Protect participants from harm
- Improve the quality of services
- Address liability issues

➢ **The goal is to find out what happened, why it happened, and what can be done to prevent it from happening again.**

What does the DDD do with the AERs?

- AERs are used in the DDD's Quality Management Process

Discovery

- Identifying the WHO, WHAT, WHEN, WHERE, WHY and HOW
- Collecting data, assessing performance

Remediation (Individual)

- Assuring immediate health and safety
- Reassessing the needs of individuals and those supporting them
- Taking action to prevent recurrence
- Informing Circle and updating ISP
- Improving quality of services and supports

Improvement (System)

- Analyzing data and spotting patterns and trends
- Establishing baselines/thresholds to assess performance
- Identifying opportunities for improvement

Expectations for AER Reporting

Who is required to fill out AERs?

- DDD Case Managers
- I/DD Waiver providers
- LASR providers
- Certified AFH caregivers
- CD Employers
- Hospital and Community Dental Services Branch staff

Reporting Requirements

- Provider must provide **verbal report** to the DDD Case Manager (or on-duty CM or CM Unit Supervisor) **within 24 hours** or the next business day of the event
  - Verbal report consists of verbally reporting the event to the Case Manager (i.e. providing detail of the event, actions taken to assure participant's immediate safety)
  - Phone messages/voicemails left during non-work hours are NOT considered a verbal report
  - You may leave a message during non-work hours but you must follow up with a phone call on the immediate next business day
- Provider must submit **written report** to the DDD Case Manager **within 72 hours** of the event

AER Policy Highlights

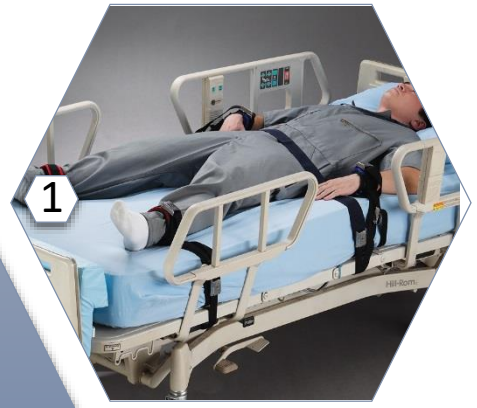
DDD Policy # 3.07 –

Adverse Events Reports for People Receiving Case Management Services with the Developmental Disabilities Division

Change to Definition of Qualifying Medical or Dental Treatment

- Related to the following adverse event types:
  - Injury from a known/unknown cause *requiring medical treatment*
  - Change in health condition *requiring medical treatment*
- What is considered reportable medical or dental treatment?
  - Treatment by ambulance or emergency medical personnel
  - Treated at Urgent Care
  - Treated at Emergency room
  - Treatment results in admission to hospital

Three (3) New Adverse Event Types



1

Any Use of Restraint

Any Use of Seclusion

2

3

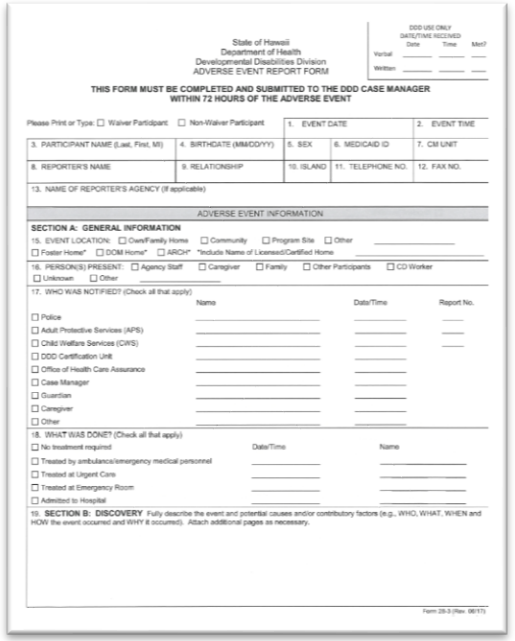
Any Use of Other Prohibited Restrictive Interventions

New AER Form

Replaces Previous Revision (12/10)

Adverse Event Report (AER)

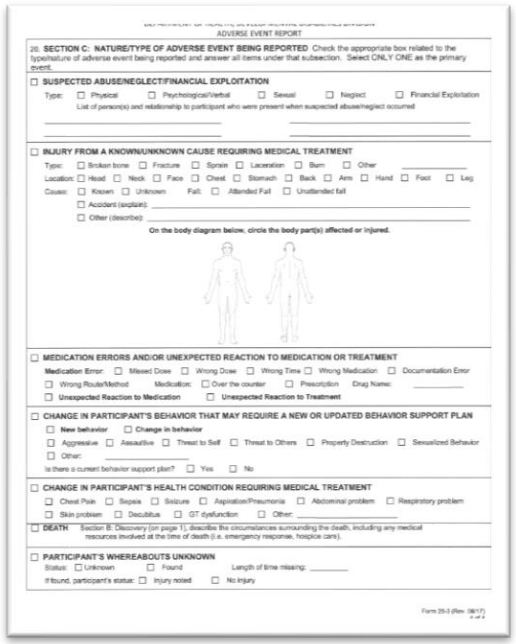
- Adverse Event Form 28-3 was revised in 6/2017
- Report consists of four (4) pages
- Divided into 6 sections


State of Hawaii
Department of Health
Developmental Disabilities Division
ADVERSE EVENT REPORT FORM

THIS FORM MUST BE COMPLETED AND SUBMITTED TO THE DDD CASE MANAGER WITHIN 72 HOURS OF THE ADVERSE EVENT

ADVERSE EVENT INFORMATION

SECTION A: GENERAL INFORMATION


SECTION C: NATURE/TYPE OF ADVERSE EVENT BEING REPORTED

SUSPECTED ABUSE/NEGLECT/FINANCIAL EXPLOITATION

INJURY FROM A KNOWN/UNKNOWN CAUSE REQUIRING MEDICAL TREATMENT

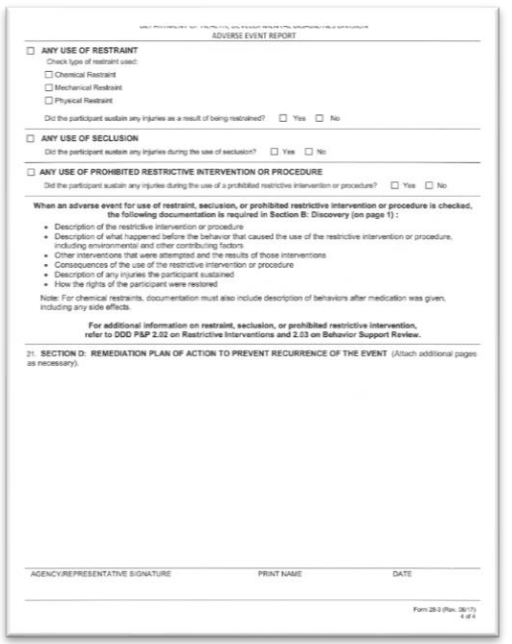
MEDICATION ERRORS AND/OR UNEXPECTED REACTION TO MEDICATION OR TREATMENT

CHANGE IN PARTICIPANT'S BEHAVIOR THAT MAY REQUIRE A NEW OR UPDATED BEHAVIOR SUPPORT PLAN

CHANGE IN PARTICIPANT'S HEALTH CONDITION REQUIRING MEDICAL TREATMENT

DEATH

PARTICIPANT'S WHEREABOUTS UNKNOWN


ANY USE OF RESTRAINT

ANY USE OF SECLUSION

ANY USE OF PROHIBITED RESTRICTIVE INTERVENTION OR PROCEDURE

When an adverse event for use of restraint, seclusion, or prohibited restrictive intervention or procedure is checked, the following documentation is required in Section B: Discovery (on page 1) :

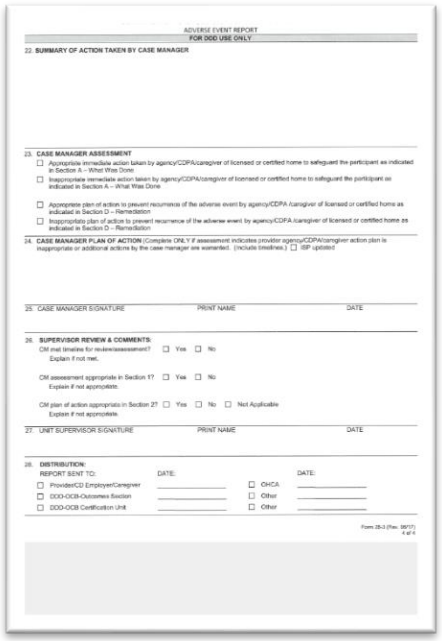
- Description of the restrictive intervention or procedure
- Description of what happened before the behavior that caused the use of the restrictive intervention or procedure, including environmental and other contributing factors
- Other interventions that were attempted and the results of those interventions
- Consequences of the use of the restrictive intervention or procedure
- Description of any injuries the participant sustained
- How the rights of the participant were restored

Note: For chemical restraints, documentation must also include description of behaviors after medication was given, including any side effects.

For additional information on restraint, seclusion, or prohibited restrictive intervention, refer to DDD PSP 2.02 on Restrictive Interventions and 2.03 on Behavior Support Review.

SECTION D: REMEDIATION PLAN OF ACTION TO PREVENT RECURRENCE OF THE EVENT (Attach additional pages as necessary).

AGENCY/REPRESENTATIVE SIGNATURE PRINT NAME DATE


ADVERSE EVENT REPORT
FOR DDD USE ONLY

22. SUMMARY OF ACTION TAKEN BY CASE MANAGER

23. CASE MANAGER ASSESSMENT

24. CASE MANAGER PLAN OF ACTION

25. CASE MANAGER SIGNATURE PRINT NAME DATE

26. SUPERVISOR REVIEW & COMMENTS:

27. UNIT SUPERVISOR SIGNATURE PRINT NAME DATE

28. DISTRIBUTION:

How the AER Changes will be Presented

1. New or substantive changes
2. Form Changes
3. AER Guidance
    - Highlights of policy and procedure changes
    - Suggestions and guidance to make reporting easier

AER – Top Section of Form (p.1)

Form Changes

State of Hawaii
Department of Health
Developmental Disabilities Division
ADVERSE EVENT REPORT FORM

DDD USE ONLY
DATE/TIME RECEIVED
Date Time Met?
Verbal
Written

THIS FORM MUST BE COMPLETED AND SUBMITTED TO THE DDD CASE MANAGER WITHIN 72 HOURS OF THE ADVERSE EVENT

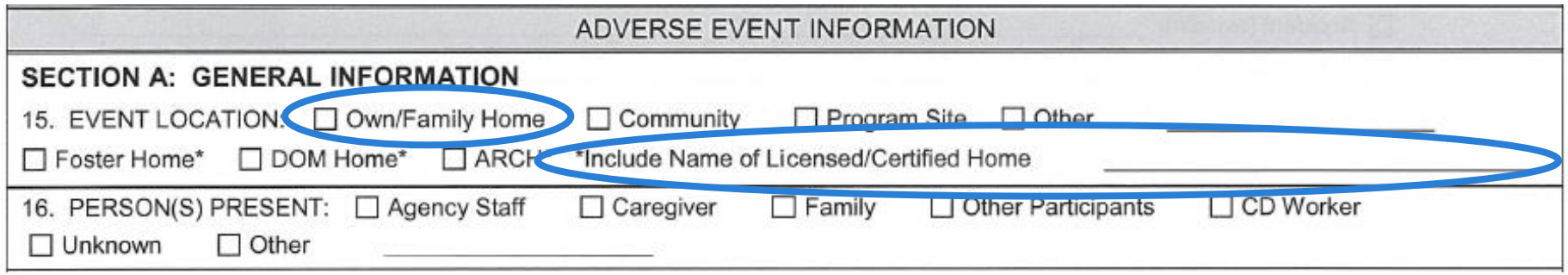
3. PARTICIPANT NAME (Last, First, MI)	4. BIRTHDATE (MM/DD/YY)	5. SEX	6. MEDICAID ID	7. CM UNIT
8. REPORTER'S NAME	9. RELATIONSHIP	10. ISLAND	11. TELEPHONE NO.	12. FAX NO.
13. NAME OF REPORTER'S AGENCY (If applicable)				

AER Guidance

- Make sure ALL information is completed and accurate
- Reporter Name: The person completing the AER form
- Supervisor's Name is no longer a required field

Section A: General Information (p.1)

Form Changes



ADVERSE EVENT INFORMATION

SECTION A: GENERAL INFORMATION

15. EVENT LOCATION: ☐ Own/Family Home ☐ Community ☐ Program Site ☐ Other _____

☐ Foster Home* ☐ DOM Home* ☐ ARCH *Include Name of Licensed/Certified Home _____

16. PERSON(S) PRESENT: ☐ Agency Staff ☐ Caregiver ☐ Family ☐ Other Participants ☐ CD Worker

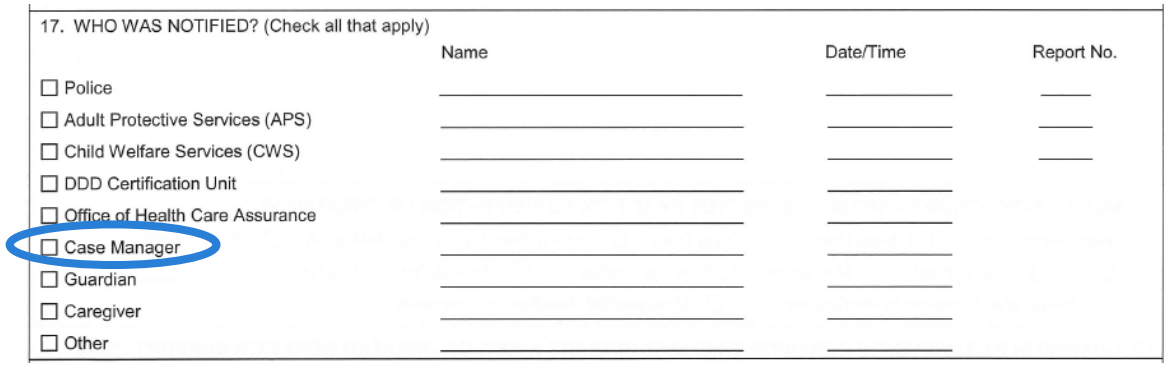
☐ Unknown ☐ Other _____

AER Guidance

- #15 Event Location –
  - Clarified: Participant's own or family home (previously, form just listed home)
  - Added: Name of Licensed/Certified Home
- Res Hab providers should indicate/verify the name the home is certified or licensed under.
- Note: If the name of the home is unknown, the report should indicate the name of the primary caregiver.
- #16 Persons Present – No Changes

Section A: General Information (p.1)

Form Changes



17. WHO WAS NOTIFIED? (Check all that apply)

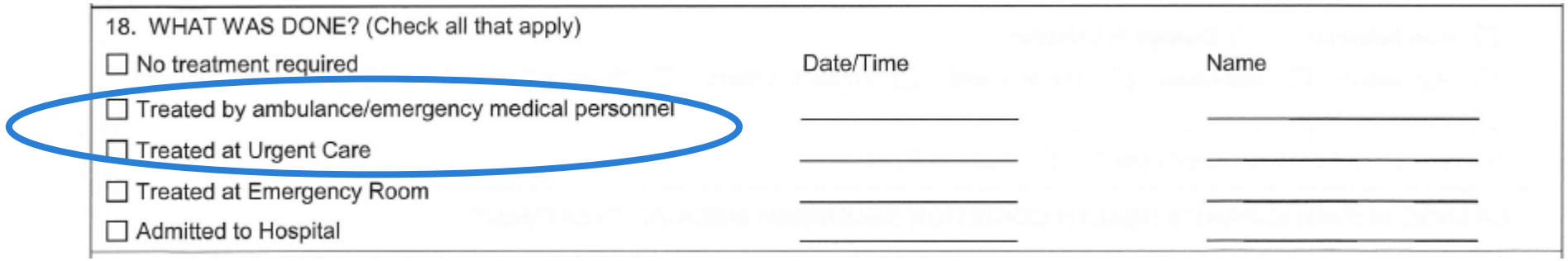
	Name	Date/Time	Report No.
☐ Police			
☐ Adult Protective Services (APS)			
☐ Child Welfare Services (CWS)			
☐ DDD Certification Unit			
☐ Office of Health Care Assurance			
☐ Case Manager			
☐ Guardian			
☐ Caregiver			
☐ Other			

NEW! AER Guidance

- Notification to Case Manager has own checkbox; Case managers should be notified regarding ALL AERs

Section A: General Information (p.1)

Form Changes



18. WHAT WAS DONE? (Check all that apply)

	Date/Time	Name
☐ No treatment required		
☐ Treated by ambulance/emergency medical personnel	_____	_____
☐ Treated at Urgent Care	_____	_____
☐ Treated at Emergency Room	_____	_____
☐ Admitted to Hospital	_____	_____

NEW! AER Guidance

- Removed:
  - Treated by Agency R.N./LPN
  - Treated by Other
  - Treated at Physician's Office
- Added:
  - Treated by Ambulance/Emergency Medical Personnel
  - Treated at Urgent Care
- If the participant received treatment from his/her primary care physician, the event is reportable to the DDD-CM but an AER is not required.

Section B: Discovery (p.1)

Form Changes

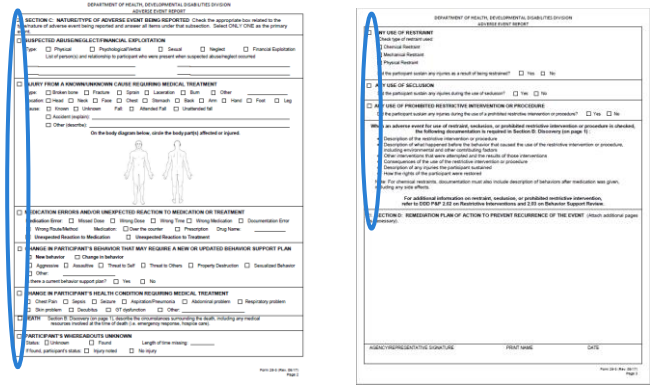
19. **SECTION B: DISCOVERY** Fully describe the event and potential causes and/or contributory factors (e.g., WHO, WHAT, WHEN and HOW the event occurred and WHY it occurred). Attach additional pages as necessary.

AER Guidance

- Enough information should be provided so that someone who does not know the participant can reasonably understand.
- Make sure you provide enough detail so there are no questions
- Address all guidance questions listed for Section B (i.e. who, what, when, how the event occurred, and why it occurred)

Section C: Nature/Type of Event (pp. 2-3)

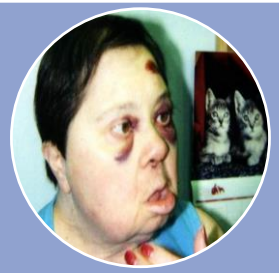
Form Changes



Select only ONE category

NEW! AER Guidance

- New adverse event types (use of restraint, seclusion, or other prohibited restrictive interventions) are required to be reported
- Information & details should already have been provided in Section B: Discovery
- When multiple events are involved, the reporter should use their best judgment to select the **most appropriate category based on significance of the event** (i.e. which event caused the most harm or most negatively impacted the participant?)



Suspected Abuse/ Neglect/Financial Exploitation

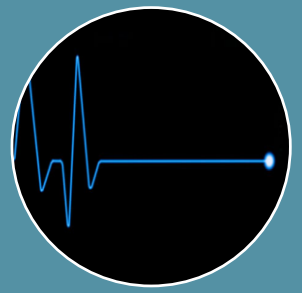
Injury Requiring Medical or Dental Treatment or Hospitalization

Medication Errors and/or Unexpected Reaction to Medication or Treatment

Change in Behavior That May Require a New or Updated Behavior Plan

Change in Health Condition Requiring Medical or Dental Treatment or Hospitalization

10 EVENT TYPES



Death

Whereabouts Unknown

NEW

Use of Restraints

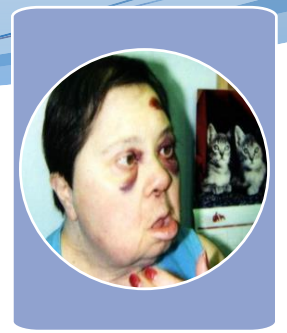
NEW

Use of Seclusion

NEW

Use of Prohibited Restrictive Intervention

Suspected Abuse, Neglect, and/or Financial Exploitation



Form Changes

☐ **SUSPECTED ABUSE/NEGLECT/FINANCIAL EXPLOITATION**

Type: ☐ Physical ☐ Psychological/Verbal ☐ Sexual ☐ Neglect ☐ Financial Exploitation

List of person(s) and relationship to participant who were present when suspected abuse/neglect occurred

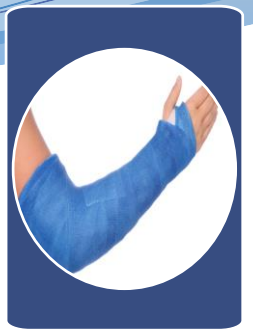
_____ _____

_____ _____

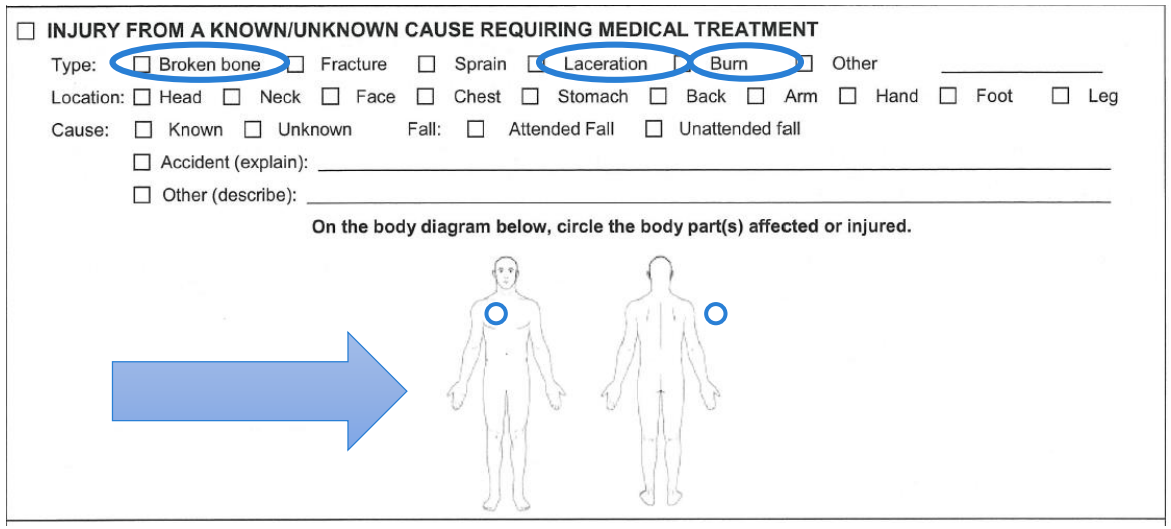
AER Guidance

- Providers should abide by all requirements in Hawaii Revised Statutes and DOH-DDD P&P:
  - HRS §350-1 re: children
  - HRS §346, Part X re: adults
  - DOH-DDD P&P #2.05, Mandatory Reporting of Abuse and Neglect (located in Appendix 5, 5A)
- Document calls/notifications to CWS/APS in the Section B: Discovery.
  - Documentation should include whether or not referral will be accepted for investigation.

Injury From a Known/Unknown Cause Requiring Medical Treatment



NEW! Form Changes



☐ INJURY FROM A KNOWN/UNKNOWN CAUSE REQUIRING MEDICAL TREATMENT

Type: ☐ Broken bone ☐ Fracture ☐ Sprain ☐ Laceration ☐ Burn ☐ Other _____

Location: ☐ Head ☐ Neck ☐ Face ☐ Chest ☐ Stomach ☐ Back ☐ Arm ☐ Hand ☐ Foot ☐ Leg

Cause: ☐ Known ☐ Unknown Fall: ☐ Attended Fall ☐ Unattended fall

☐ Accident (explain): _____

☐ Other (describe): _____

On the body diagram below, circle the body part(s) affected or injured.

NEW! AER Guidance

- Type of Injury: Removed bruise and cut from; Added broken bone, laceration, and burn
- Location of Injury: Added body diagram to assist with indicating where the person was injured
- Cause: Removed “another person”
- Medical treatment now defined as rendered by ambulance, EMT, urgent care, Emergency Room, or resulting in hospitalization

Medication Errors and/or Unexpected Reaction to Medication or Treatment

Form Changes

☐ **MEDICATION ERRORS AND/OR UNEXPECTED REACTION TO MEDICATION OR TREATMENT**

Medication Error: ☐ Missed Dose ☐ Wrong Dose ☐ Wrong Time ☐ Wrong Medication ☐ Documentation Error

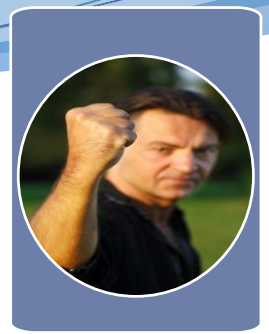
☐ Wrong Route/Method Medication: ☐ Over the counter ☐ Prescription Drug Name: _____

☐ **Unexpected Reaction to Medication** ☐ **Unexpected Reaction to Treatment**

AER Guidance

- Removed: “Adverse/Non-Adverse” and “Other” category
- Added: “Documentation Error”
- Revised: “Did not give” changed to “Missed Dose”
- Documentation error – limited to errors on the Medication Administration Record (MAR) which can be verified (e.g. counting medications in prescribed medication container)
- Missed dose – any time medication was not given; includes failure to document medication administration

Change in Behavior That May Require a New or Updated Behavior Support Plan



NEW! Form Changes

☐ CHANGE IN PARTICIPANT'S BEHAVIOR THAT MAY REQUIRE A NEW OR UPDATED BEHAVIOR SUPPORT PLAN

☐ New behavior ☐ Change in behavior

☐ Aggressive ☐ Assaultive ☐ Threat to Self ☐ Threat to Others ☐ Property Destruction ☐ Sexualized Behavior

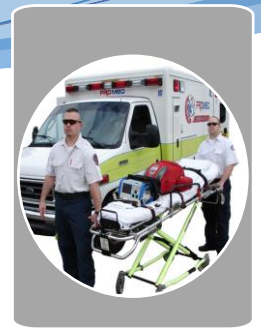
☐ Other: _____

Is there a current behavior support plan? ☐ Yes ☐ No

NEW! AER Guidance

- Added: "Aggressive" & "Sexualized Behavior"
- Removed: Questions related to use of restraints (now has it's own category)
  - Use of restraints now clarified in policy
- AERs focus on new behaviors or behavior that has changed in frequency, intensity, or duration
  - Form better aligns with Positive Behavior Support and Behavior Supports Review policies
  - Addresses situations when behaviors are escalating, new behaviors are emerging, and/or behaviors are not being addressed by current BSP

Change in Health Condition Requiring Medical Treatment



NEW! Form Changes

☐ CHANGE IN PARTICIPANT'S HEALTH CONDITION REQUIRING MEDICAL TREATMENT

☐ Chest Pain ☐ Sepsis ☐ Seizure ☐ Aspiration/Pneumonia ☐ Abdominal problem ☐ Respiratory problem

☐ Skin problem ☐ Decubitus ☐ GT dysfunction ☐ Other: _____

NEW! AER Guidance

- Removed: Headache, dizziness, fainted
- Added: Sepsis, Aspiration/Pneumonia, Respiratory Problem, GT
- Medical treatment now defined as treatment rendered by ambulance, EMT, urgent care, Emergency Room, or resulting in hospitalization
  - MD visits (scheduled or unscheduled) no longer meet threshold for critical event (required for AER submission) UNLESS it results in hospitalization
  - If medical treatment is scheduled (e.g. scheduled out-patient procedure), an AER is not needed since remediation is taking place

Death

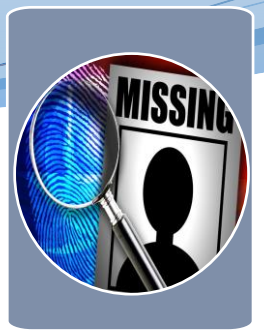
Form Changes

☐ DEATH	Section B: Discovery (on page 1), describe the circumstances surrounding the death, including any medical resources involved at the time of death (i.e. emergency response, hospice care).

NEW! AER Guidance

- Removed expected and unexpected death
- Except for checking event type, no information captured in this section. All information should be included in Discovery, Section B.
- In the Discovery Section of the AER, include description of circumstances and medical resources involved.
- Old form asked for the cause and date of death
- New form asks you to describe the circumstances surrounding the death and the medical resources involved (e.g. participant had cancer, treatment was unsuccessful, received in-home hospice care and passed away two weeks later).

Whereabouts Unknown



Form Changes

☐ **PARTICIPANT'S WHEREABOUTS UNKNOWN**

Status: ☐ Unknown ☐ Found Length of time missing: _____

If found, participant's status: ☐ Injury noted ☐ No injury

AER Guidance

- An AER should be submitted anytime participant cannot be not found within the perimeter of the service location
- Reports should be submitted anytime whereabouts are unknown; not limited to when a participant is still missing
- Submit an AER if an individual cannot be found within the perimeter of the service location in a reasonable amount of time

AER - New Event Types (p. 3)

- Review of DDD Policy #2.02 – Restrictive Interventions
  (Waiver Standards Appendix 4B)

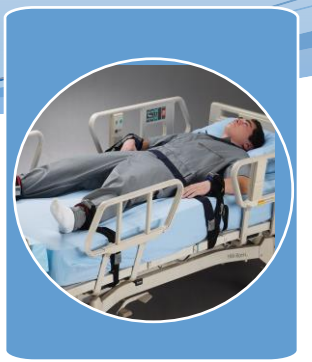
Restrictive Interventions – practice that limits a participant's freedom of movement, access to other locations, property, individuals, or rights

- Chemical Restraint
- Mechanical Restraint
- Physical Restraint
- Prohibited Restrictive Interventions

Restrictive Interventions

Chemical restraint	Prescribed Psychotropic medications	Used routinely for behavior control with no DSM diagnosis	PRN medications used to restrict movement or sedate individual
Mechanical Restraint	Intervention involving a device, material, or equipment	Involuntarily applied to body or immediate environment	Immobilizes, restricts, limits, or reduces movement to prevent harm
Physical Restraint	Intervention in which physical force is applied	Involuntarily restricts freedom of movement	Involuntarily restricts normal access to a portion of the body
Prohibited Restrictive Interventions	Threats or punishment to change behavior	Used for purpose of discipline, retaliation, or staff convenience	Includes seclusion, aversive procedures, and restraints

NEW! Any Use of Restraint



NEW! Form Changes

☐ **ANY USE OF RESTRAINT**

Check type of restraint used:

☐ Chemical Restraint

☐ Mechanical Restraint

☐ Physical Restraint

Did the participant sustain any injuries as a result of being restrained? ☐ Yes ☐ No

NEW! AER Guidance

- New P & Ps: Restrictive Interventions (P&P #2.02, Waiver Standards Appendix 4B) & Behavior Support Review (P&P #2.03, Waiver Standards Appendix 4C)
- Previously, use of physical restraints were captured in the Change in Behavior section
- If the intervention is NOT considered a restraint, an AER is NOT required
- Report ALL events involving restraints
- When in doubt, report it!

What is NOT considered a restraint?

Interventions used for the purpose of:	• Conducting routine physical or dental examinations • Diagnostic tests • Completing a medical or dental treatment procedure
Device used to protect the participant's safety:	• As indicated in the ISP per a physician's recommendation • Reviewed by the Behavior Supports Review Committee (BSRC) • Includes vehicular passenger restraint systems required by law
Prescribed psychotropic medications when following criteria is met:	• Prescribed for treatment of diagnosed disorder found in DSM • Adjusting dose or new medications to achieve better symptom control • Prescribed to control seizures • Used for medical or dental procedures

NEW! Any Use of Seclusion

NEW! Form Changes

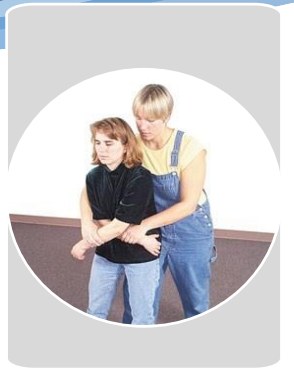
☐ **ANY USE OF SECLUSION**

Did the participant sustain any injuries during the use of seclusion? ☐ Yes ☐ No

NEW! AER Guidance

- Seclusion is **PROHIBITED** and shall not be utilized with participants
  - Defined as a restrictive intervention in which a person is involuntarily confined in a room or area from which they are prevented from having contact with others or leaving by closing a door or using another barrier.
  - Refer to Restrictive Interventions P&P (P&P #2.02, Waiver Standards Appendix 4B)
- Technically a prohibited restrictive intervention
- Carved out as own category
- If seclusion was used as an intervention, this event type should be selected (vs. selecting use of a prohibited restrictive intervention)

NEW! Any Use of Prohibited Restrictive Intervention or Procedure



NEW! Form Changes

☐ **ANY USE OF PROHIBITED RESTRICTIVE INTERVENTION OR PROCEDURE**

Did the participant sustain any injuries during the use of a prohibited restrictive intervention or procedure? ☐ Yes ☐ No

NEW! AER Guidance

- Report ALL events involving prohibited restrictive intervention(s).
  - Refer to Restrictive Interventions P&P (P&P #2.02, Waiver Standards Appendix 4B)
  - List of prohibited interventions in P&P is NOT an exhaustive list
- Use of ANY restrictive intervention must comply with P&P for Positive Behavior Supports (P&P # 2.01, Waiver Standards Appendix 4A) and Behavior Support Review (P&P #2.03, Waiver Standards Appendix 4C)
- Seclusion is a prohibited restrictive intervention but has its own event category. If seclusion is used as intervention, select Use of Seclusion as event type

NEW! ALL AERs Involving Restraints, Seclusion, or Restrictive Intervention

NEW! Form Changes

When an adverse event for use of restraint, seclusion, or prohibited restrictive intervention or procedure is checked, the following documentation is required in Section B: Discovery (on page 1) :

- Description of the restrictive intervention or procedure
- Description of what happened before the behavior that caused the use of the restrictive intervention or procedure, including environmental and other contributing factors
- Other interventions that were attempted and the results of those interventions
- Consequences of the use of the restrictive intervention or procedure
- Description of any injuries the participant sustained
- How the rights of the participant were restored

Note: For chemical restraints, documentation must also include description of behaviors after medication was given, including any side effects.

For additional information on restraint, seclusion, or prohibited restrictive intervention, refer to DDD P&P 2.02 on Restrictive Interventions and 2.03 on Behavior Support Review.

NEW! AER Guidance

- Additional documentation requirements to be written in Section B: Discovery (page 1)
- Make sure the Discovery section documents all information requested

Section D: Remediation (p.3)

Form Changes

21. **SECTION D: REMEDIATION PLAN OF ACTION TO PREVENT RECURRENCE OF THE EVENT** (Attach additional pages as necessary).

AGENCY/REPRESENTATIVE SIGNATURE | PRINT NAME | DATE

AER Guidance

- Goal is to find out what you plan to do to ensure the event will not happen again
  - What corrective actions were taken?
  - Could the event have been prevented?
  - What is your plan to prevent it from reoccurring?
  - Does it connect to what you have presented in Discovery?
  - Are updates to ISP necessary? If so, have you made recommendations for ISP update/revision?

AER Review Process

Written AER is received by DDD CM

- Within 72 hours of event

AER is assessed by CM; CM develops Plan of Action if necessary

- Upon receipt of written AER

CM submits to CM Unit Supervisor for review

- Within 2 days of receiving report from provider

Unit Supervisor sends response to provider and submits to OCB for review

- Within 2 days of receiving report from CM

AER should be completed and distributed by DDD **within 5 working days** of receipt.

Activity: Examples

Scenario Activity: Is this a reportable AER?

Scenario:

Jack had multiple seizures so his caregiver took him to his neurologist. Neurologist increased his medication dosage to better manage seizures.

Correct Answer:

NO. This is a non-reportable event.

Jack did not receive medical treatment under the new definition; medications in this situation are not considered a chemical restraint.

Scenario Activity: Is this a reportable AER?

Scenario:

Jill has a history of explosive outbursts. She attacked her mother this morning and cut her finger on a piece of glass. This is the first time she has ever hurt someone. Her direct support worker assisted her to take her Prozac as ordered (ongoing medication prescribed for Intermittent Explosive Disorder) then took her to the doctor.

Correct Answer:

YES. This is a reportable event. This is a **Change in Behavior** that may Require a New or Updated Behavior Support Plan (based on new behavior AND increase in intensity/ severity of the behavior). Medications in this situation are not considered a chemical restraint and MD visit is not considered adverse event under the new definition of medical treatment.